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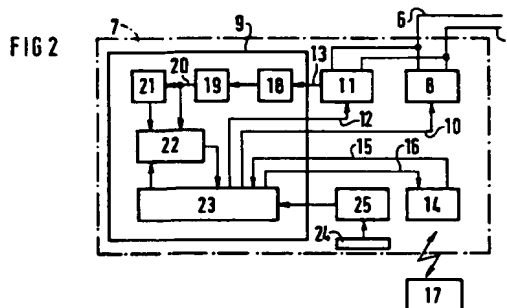
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⑤④ **Rate-responsive heart stimulator.**

57) A rate-responsive heart stimulator with a variable stimulation interval is described, said heart stimulator containing a measurement device (11) which generates a measurement signal corresponding to the volume of blood in a heart during the blood-filling phase (diastole) and a comparator (22) which compares the measurement signal with a defined threshold value corresponding to a defined degree of blood filling, generating a control signal when the measurement signal reaches the threshold value, said control signal representing the time elapsing since the last stimulation pulse, and controlling the heart stimulator's stimulation interval.



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This invention relates to a rate-responsive pacemaker comprising at least one pulse generator which generates and emits stimulation pulses with a variable stimulation interval to a heart, a measurement device which generates a measurement signal corresponding to blood flow into or the volume of blood in a heart chamber and a control device which controls the pulse generator's stimulation intervals depending on the measurement signal.

A known heart stimulator is described in US-A-4.686.987, said heart stimulator containing an impedance meter which measures heart impedance, a parameter which is proportional to ventricular volume and, accordingly, the volume of blood in the heart. The heart's stroke volume in each heart cycle is derived from the impedance signal, and the heart stimulator is controlled in such a way that the stimulation rate causes the stroke volume to remain as constant as possible. So in the known heart stimulator, any change in stroke volume indicates a change in the patient's level of physical activity and causes a change in the stimulation rate, thereby counteracting the change in stroke volume.

Another known heart stimulator is described in US-A-4.535.774 in which stroke volume is established either by measuring blood flow into the heart or by measuring impedance. The measured stroke volume is then used for setting a heart rate. A relationship between stroke volume and heart rate, in which stroke volume increases when the heart rate increases, is utilized for optimizing cardiac function as much as possible, whereby the amount of blood pumped out of the heart every minute is sufficient for the body's needs without the heart rate becoming excessively fast.

So, both the known heart stimulators measure stroke volume and then utilize this parameter, or changes in same, for establishing an appropriate stimulation rate and then imposing that rate on the heart. The heart stimulator according to the first document has the disadvantage that heart rate rises rapidly when there is a need for a large volume of blood per unit of time (cardiac output). This problem is admittedly solved with a heart stimulator according to the second document in which stroke volume is allowed to change and increase when the heart rate increases, thereby retaining cardiac output without an excessively fast stimulation rate. In view of the cardiac cycle's normal course of events, however, stroke volume is not particularly suitable for use in setting a heart rate in this way. When blood in the heart has been expelled in a normal cardiac cycle and the muscle relaxes for refilling, the influx of blood into the heart is governed by blood pressure in the vascular system. Blood flows rapidly into the heart at the

beginning of diastole. But the flow ultimately ceases when the heart is full of blood, i.e. when pressure in the heart and vascular system equalize. A slight change in stroke volume could therefore require a major change in rate. In addition, the influx of blood into the heart depends on the stimulator wearer's physical and mental condition. At rest, the influx of blood into a patient's heart is slower at the beginning of diastole than during physical exercise or stress.

The object of the invention is to produce a rate-responsive heart stimulator which effectively optimizes cardiac output on the basis of the volume of blood in the heart.

Such a heart stimulator is achieved in accordance with the invention in that the control device contains a comparator which, during the heart's blood-filling phase (diastole), compares the measurement signal with a defined threshold value corresponding to a defined degree of blood filling of the heart chamber and which generates a control signal when the measurement signal exceeds the threshold value, said control signal representing the time elapsing since emission of the last stimulation pulse and controlling the pulse generator's stimulation interval.

This results in a heart stimulator which in essential respects imitates the function of a normal heart. The influx of blood into the heart at the start of diastole is slower when the body is at rest, and refilling time is therefore longer, corresponding to a slower rate. When the body is subjected to heavy physical exertion or mental stress causing the pressure of blood in the vascular system to rise, the rate of blood flow into the heart increases accordingly during diastole, as well as heart rate. In contrast to the known heart stimulators, it is not necessary for a heart stimulator according to this invention to calculate a heart rate on the basis of stroke volume and then impose that rate on the heart. For example, measuring the flow of blood into the heart and having the threshold value consist of a flow value is sufficient. Since the flow of blood into the heart completely ceases when the heart has filled with blood, the threshold value corresponds to a specific degree of filling. Here, measuring blood flow in the latter part of diastole is enough to obtain the control signal.

One refinement of the heart stimulator is achieved in accordance with the invention when the comparator is connected to the pulse generator, and the pulse generator emits a stimulation pulse when it receives the control signal.

A heart stimulator operating according to this principle emits a stimulation pulse as soon as an adequate degree of blood filling is achieved in the heart.

It would be an advantage here if the control device further contained a means for delaying transmission of the control signal to the pulse generator by a defined delay interval. Operation would then be more like the operation of a normal heart in which there is a delay between cessation of blood flow into the heart and a heart beat. The delay interval also makes some variation in the stroke volume possible, since the flow of blood into the heart varies according to the level of activity. From the point at which the threshold value is reached until the delay interval has expired, the extra influx of blood will depend on the level of activity. In addition, a faster initial influx of blood during diastole increases myocardial stretching, thereby enabling the heart to receive more blood.

In this context, it would be an advantage if the control device comprised a means for measuring the time elapsing between emission of the latest stimulation pulse and generation of the control signal and if the defined delay interval were set by the control device, according to the time measured.

As an alternative to transmission of the control signal directly to the pulse generator, the heart stimulator according to the invention can be devised so the control device comprises a timecounter, which measures the time elapsing between the latest emitted stimulation pulse and re-generation of the control signal, and a timer activated when a stimulation pulse is emitted and which times an entered stimulation interval, whereupon an activation signal is transmitted to the pulse generator which emits a stimulation pulse, the time measured then being fed to the timer to serve as the next stimulation interval.

As a result, the stimulation rate would be set with a delay, i.e. one stimulation interval. In this context, it would be an advantage if the control device further comprised a means for changing by a defined time interval the time serving as the next stimulation interval. This would make it possible to monitor stimulation intervals in a different way than when the control signal is sent from the comparator straight to the pulse generator. Intervals could be e.g. prolonged or shortened, depending on their relationship to preceding intervals. This would prevent rapid changes in the stimulation rate. A slow change in the rate when the level of activity changes is more like the way a healthy heart operates.

In this context, it would be an advantage if the control device set the interval which changes the next stimulation interval depending on the time measured by the timer.

A refinement of the second alternative according to the invention is achieved when the control device comprises an averager, which forms a floating average of a defined number of preceding

stimulation intervals, and the current average is sent to the timer to serve as the next stimulation interval.

Utilization of an average value governed by a defined number of preceding stimulation intervals ensures that excessively rapid changes in the stimulation interval are not imposed on the heart.

It would be an advantage if the control device measured impedance in the heart chamber, since the impedance signal is directly related to changes in the influx of blood.

An advantageous refinement is obtained when the control unit comprises a differentiator which derives the measurement signal, and the comparator compares the derived measurement signal with the threshold value. The derivative of the impedance signal corresponds to the velocity of blood flow into the heart. This flow depends on the blood pressure gradient prevailing between the vascular system and the heart at the start of diastole when the myocardium relaxes. So, influx is fastest at the beginning of diastole and slows thereafter. The derivative of the impedance signal therefore initially increases rapidly and approaches an extreme value. The derivative is negative when impedance is measured. The derivative then declines and approaches null. The threshold value consists of a value passed by the derivative as it approaches null after falling from its extreme value. Stroke volume and heart rate will vary in a natural way, since a faster initial flow causes the heart to fill with more blood at the same time as the stimulation interval is shortened.

In conjunction herewith, it would be an advantage if the control device comprised a peak value detector, which detects the derivative's extreme value during diastole, and a means for generating the threshold value so it constitutes a defined part of the extreme value.

The derivative's extreme value during diastole indicates the most rapid influx of blood into the heart, and this value is then utilized as the starting point for establishing a threshold value which designates a defined degree of heart filling. The extreme value corresponds to the derivative's minimum when impedance is measured. In this way, the function of the heart is made more independent of stroke volume as such and dependent on the phase of the heart's diastole. When the threshold value depends on the derivative's extreme value, function is additionally refined compared to the situation with a fixed threshold value. The threshold value could e.g. be set at 25% of the derivative's extreme value.

A refinement of the heart stimulator is achieved in accordance with the invention when the heart stimulator contains an additional measurement device, which measures a physiological variable, and

a means for determining the threshold value according to the physiological variable measured.

There are a plurality of known physiological variables which are affected in some way by the patient's level of activity, variables such as blood temperature, blood oxygen, respiratory rate, acceleration of the body in movement etc. Utilization of a physiological variable in determining the threshold value results in more refined control of the heart stimulator. When the derivative of the measurement signal is employed as a parameter for blood filling, the physiological variable can be used for establishing how much of the derivative's extreme value the threshold value is to constitute. The heart stimulator also becomes more effective, since the physiological variable only affects the degree of filling to be achieved and does not supply a competitive stimulation rate.

To make the heart stimulator as safe as possible, the control device could advantageously comprise a stimulation interval timer, which times each stimulation interval, and a means for limiting the next stimulation interval so it does not become shorter than a first defined part of the timed stimulation interval nor longer than the timed stimulation interval by more than a second defined part of the timed stimulation interval.

Thus, a stimulation interval can be set at e.g. 90 - 110% of the latest stimulation interval. This means that the rate is unable to change too quickly when there is a change in the level of activity.

Three embodiments of the heart stimulator will be described, referring to the figures, whereby:

- FIG. 1 schematically depicts a first embodiment of a heart stimulator according to the invention, connected to a heart;
- FIG. 2 shows the first embodiment in greater detail in a block diagram;
- FIG. 3 illustrates the operation of the first embodiment of the heart stimulator in a diagram;
- FIG. 4 shows a second embodiment of the heart stimulator in a block diagram;
- FIG. 5 illustrates the operation of the second embodiment of the heart stimulator in a diagram; and
- FIG. 6 shows a third embodiment of a heart stimulator according to the invention in a block diagram.

The heart stimulator in FIG. 1 consists of a bipolar pacemaker 1, which has a tip electrode 2 and a ring electrode 3, connected via a first electrode conductor 5 and a second electrode conductor 6 respectively to a heart 4. The pacemaker 1 generates and emits stimulation pulses across the heart 4 through the electrodes 2, 3 in order to improve cardiac dysfunction in a patient.

In FIG. 2 is shown the first embodiment of the pacemaker 1 in a block diagram. Pacemaker electronics are contained in a pacemaker enclosure 7. A pulse generator 8 is connected to the first electrode conductor 5 and the second electrode conductor 6. The pulse generator 8 generates and emits stimulation pulses with a defined amplitude and duration. The time at which stimulation pulses are emitted, as well as the amplitude and duration of same, is controlled by a control device 9 to which the pulse generator 8 is connected by a stimulation pulse signal conductor 10 and whose design will be described in greater detail below.

An impedance meter 11 is also connected to the first electrode conductor 5 and the second electrode conductor 6 to measure impedance in the ventricle. Here, the impedance meter intermittently emits a current pulse, e.g. a 5  $\mu$ A pulse with a frequency of 4 kHz, between the tip electrode 2 and the ring electrode 3. Voltage between the two electrodes 2, 3 is measured, and a measurement signal is obtained which corresponds to impedance in the ventricle. Activation of the impedance meter 11 and the setting of the current pulse's amplitude and frequency are controlled by the control device 9 which is connected to the impedance meter 11 by a control conductor 12. The measurement signal is transmitted from the impedance meter 11 to the control device 9 via a signal conductor 13 for additional signal conditioning, as described below. Since blood has a lower impedance than heart tissue, the impedance signal will be at a minimum at the end of diastole and at a maximum at the end of systole.

In the control device 9, the measurement signal is fed from the impedance meter 11 to a bandpass filter 18 which filters out the part of the measurement signal corresponding to the volume of blood in the ventricle. The impedance meter 11 is active during at least a part of the heart's 4 blood-filling phase (diastole). The filtered measurement signal is derived in a differentiator 19 and sent through a signal conductor 20 to a peak value detector 21 and a comparator 22. The derivative becomes negative when impedance abates during diastole. So, the peak value detector 21 senses the derivative's minimum value and transmits this value to the comparator 22. The derived measurement signal is compared in the comparator 22 to a threshold value corresponding to optimum blood-filling at a defined stimulation point in time and, thus, a defined stimulation interval. In this embodiment, the threshold value consists of a part of the derivative's peak value and is obtained from a control unit 23. This part can be set at e.g. 25%, but the part of the derivative's minimum value which the threshold value constitutes is variable so pacemaker operation can be optimized. The pacemaker contains an ac-

tivity sensor 24, a piezoelectric crystal glued to the inside of the enclosure 7 in this instance, for controlling the magnitude of the part. The piezoelectric crystal generates signals on the basis of changes in the pressure exerted against the enclosure 7 caused by the pacemaker wearer's body movements. The signal is transformed in a signal converter 25 into an activity signal sent to the control unit 23. The magnitude of the part is governed by the activity signal in such a way that the part is e.g. 25% in rest and 40% when the level of activity is high. Having a higher value for the part when there is a high level of activity is because the flow of blood in diastole is faster in high activity, making the derivative's minimum value more negative.

Thus, the derived measurement signal is compared in the comparator 22 with the measured minimum value for the derivative. When the derived measurement signal reaches the threshold value, a control pulse is generated by the comparator 22 and sent to the control unit 23. The control signal is delayed by the control unit 23, and the time elapsing between the latest stimulation pulse and generation of the control pulse is compared to the latest stimulation interval. If the time, plus the delay, is shorter than a defined part of the latest stimulation interval, e.g. 90%, the control unit 23 does not send the control signal to the pulse generator 8 until the defined part of the last stimulation interval has expired. This is to prevent an excessively large increase in the rate of stimulation. In the corresponding manner, the control unit 23 sends a control signal to the pulse generator 8 if the comparator 22 fails to generate a control signal before the latest stimulation interval plus a second defined part of the latest stimulation interval, e.g. 10%, expires. The purpose here is to keep the rate of stimulation from dropping too much when the level of activity declines. The control unit 23 also limits the rate of stimulation by only allowing rates within a specific interval, e.g. 60 to 170 beats/minute.

A telemetry unit is connected to the control device 9 by two signal conductors 15 and 16, and the control device 9 transmits information and program parameters, via the telemetry unit 14, to/from an extracorporeal programming unit 17 which a doctor can operate.

FIG. 3 illustrates in a diagram operation of the pacemaker in FIG. 2. Three time axes 26a - c show the derivative 27 of the impedance signal Z, control signals 28a - d from the comparator 22 and stimulation pulses 29a - e from the pulse generator 8. For the sake of clarity, the derivative 27 is shown for the entire cardiac cycle, even though determination of the derivative 27 is only necessary for a part of diastole. Since blood is a better electrical conductor than heart tissue, impedance drops dur-

ing diastole when the heart 4 fills with blood and increases during systole when the heart is emptied of blood. The derivative 27 therefore becomes negative during diastole and positive during systole. A minimum value  $M_{n-1}$  for the derivative 27 is measured during diastole in the peak value detector 21. When the derivative signal approaches null as the flow of blood into the heart 4 declines, it passes a threshold value  $T_{n-1}$  constituting a specific part of the minimum value  $M_{n-1}$ . The comparator 22 then emits a control signal 28a which, after a preset delay I, results in emission of stimulation pulse 29a. The emitted stimulation pulse 29a also starts a new stimulation interval  $I_n$ . A minimum value  $M_n$  for the derivative signal 27 is again set during diastole, and a new control signal 28b is generated, when the threshold value  $T_n$  is reached, leading to a new stimulation pulse 29b after the delay interval I. The stimulation interval  $I_{n+1}$  continues in the corresponding manner with the setting of the minimum value  $M_{n+1}$ , the passing of the threshold value  $T_{n+1}$ , which results in a control signal 28c and a stimulation pulse 29c after the delay interval I. During the stimulation interval  $I_{n+2}$ , the control signal 28d occurs so early in the interval  $I_{n+2}$  that the stimulation interval  $I_{n+2}$ , even with the delay I, would be less than 90% of the last stimulation interval  $I_{n+1}$  if a stimulation pulse were emitted after the delay I. So the stimulation pulse 29d is not emitted until 90% of the stimulation interval  $I_{n-1}$  has elapsed. During the stimulation interval  $I_{n+3}$ , the opposite occurs. The comparator 22 has not generated any signal when 110% of the stimulation interval  $I_{n+2}$  has elapsed, so a stimulation pulse 29e is emitted without the generation of any control signal. When the stimulation pulse 29e is emitted, the derivative rapidly passes the threshold value  $T_{n+3}$ , and the comparator 22 generates a control signal 28e which however, is ignored by the control device 9.

A second embodiment of the pacemaker 1 is illustrated in FIG. 4. The tip electrode 2 and the ring electrode 3 are connected by the first electrode conductor 5 and the second electrode conductor 6 respectively to a pulse generator 30 in a pacemaker enclosure 31. A heart detector 32 and an impedance meter 33 are also connected to the first electrode conductor 5 and the second electrode conductor 6. The heart detector 32 senses the electrical activity of the heart 4 in order to detect any spontaneous heart responses and transmit information on same to a control unit 34 in a control device 35. Emission of a stimulation pulse is inhibited if any spontaneous response is detected in the heart.

The impedance meter 33 is controlled in the same way as the impedance meter 11 shown in FIG. 2 and, thus, generates a measurement signal which is transmitted to a bandpass filter 36 in the

control device 35 for filtering out the part of the signal which corresponds to the volume of blood in the heart 4. The filtered signal is derived in a differentiator 37 and sent to a peak value detector 38 and a comparator 39. The derivative's minimum value is determined in the peak value detector and is also sent to the comparator 39. From the control unit 34, the partial value governing the threshold value is sent to the comparator 39 in which it is compared to the derived measurement signal. An activity sensor, attached to the exterior of the pacemaker enclosure 31, is also employed in this embodiment and connected by a sensor conductor 43 coupled to a measurement device 44 in the pacemaker 1. In this instance, the sensor could e.g. consist of a thermometer or blood oximeter. The sensor signal is transformed in the measurement device 44 into an activity signal which is sent to the control unit 34 to change the partial value yielding the threshold value.

When the derived measurement signal reaches the threshold value, the comparator 39 generates a control signal which is sent to a delay circuit 40 and the control unit 34. The delay circuit 40 transmits the control signal after a specific delay controlled by the control unit 34. Here, the delay depends on the interval to be prolonged, i.e. the control unit contains a timer which measures the time elapsing from the last stimulation or spontaneous event to generation of a control signal and, on the basis thereof, sets the prolongation as a given percent of the timed interval.

The delayed control signal is sent to a time-counter 41 and stops a timing triggered by any signal emitted by the control unit 34 at the same time as a stimulation pulse or a detected spontaneous heart response. The timed interval serves as the duration of the next stimulation interval and is sent to the control unit 34 and to a timer 42.

The control unit 34 compares measured time with the ongoing stimulation interval. If too short or too long, the measured time is adapted to the ongoing stimulation interval. Since the ongoing stimulation interval consists of the time measured for the last stimulation interval, this time is available in the control unit 34 for direct comparison. After the timer 42 times the ongoing stimulation interval, a control pulse is sent to the control unit 34 and to the pulse generator 30, ordering the latter to emit a stimulation pulse. Here, the control unit 34 activates the timer 42 which begins timing the timed interval, or an interval sent from the control unit 34, whereupon it serves as the stimulation interval.

If a spontaneous heart response is detected by the heart detector 32 before the timer 42 has timed the stimulation interval, the control unit 34 sends an inhibitory signal to the pulse generator 30 and a signal to the timer 42, zeroing it, whereupon the

timer begins timing the next stimulation interval.

A telemetry unit 45 communicates with the control unit 34 in the control device 35 and transmits information and program parameters to/from an extracorporeal programming unit 46.

FIG. 5 illustrates in a diagram the operation of the pacemaker 1 according to the second embodiment in FIG. 4. Four time axes 47a - d show the impedance derivative 48, control signals 49a - e, stimulation pulses 50a - d and heart responses 51a - f.

The stimulation pulse 50a on the time axis 47c induces a heart response 51a shown on time axis 47d. The stimulation pulse 50a also starts the stimulation interval  $I_n$ . The minimum negative derivative  $M_{n+1}$  for the derivative signal 48 is reached during diastole, and the threshold value  $T_{n+1}$  is reached when the derivative rises toward null, whereupon a control signal 49a is generated by the comparator 39. A delay interval  $I$  is added to the time elapsing between the last stimulation pulse 50a and generation of the control signal 49a and the next stimulation interval  $I_{n+1}$ . When the stimulation interval  $I_n$  expires, a stimulation pulse 50b is emitted which induces a heart response 51b and initiates timing of the stimulation interval  $I_{n+1}$  and the stimulation interval  $I_{n+2}$ . The derivative's minimum value  $M_{n+2}$  and signal transmission at the threshold value  $T_{n+2}$  are set. A control signal 49b is generated, and the stimulation interval  $I_{n+2}$ , with the addition of the delay interval  $I$ , is set. When the stimulation interval  $I_{n+1}$  expires, a stimulation pulse 50c is emitted which induces a heart response 51c. A spontaneous heart response 51d occurs during the stimulation interval  $I_{n+2}$ , so no stimulation pulse is emitted at the end of the stimulation interval  $I_{n+2}$ . However, the next stimulation interval  $I_{n+3}$  is set in the same way as before, following determination of the minimum value  $M_{n+3}$  and the threshold value  $T_{n+3}$ , by generation of the control signal 49c. A spontaneous heart response 51e also occurs in the stimulation interval  $I_{n+3}$  before the stimulation interval  $I_{n+3}$  elapses, and no stimulation pulse is emitted. However, the next stimulation interval  $I_{n+4}$  is set in the same way as before. No spontaneous heart responses occur in the next stimulation interval  $I_{n+4}$ , so a stimulation pulse 50d is emitted when the stimulation interval  $I_{n+4}$  elapses, inducing a heart response 51f. The next stimulation interval  $I_{n+5}$  is simultaneously set in the same way as before.

Even in this embodiment, the stimulation interval set is compared with the latest stimulation interval in order to limit changes in the rate. If, for example, a ventricular extrasystole (VES) occurs after half the stimulation interval, the stimulation interval set (i.e. the next interval) will amount to 90% of the present interval, not 50%.

An averager can also be coupled between the timecounter 41 and the timer 42 in FIG. 4 for calculating a floating average value for a defined number of preceding stimulation intervals. Prolongation of the timed interval achieved by the delay circuit 40 can also be attained by measurement of the time elapsing between the stimulation pulse and generation by the comparator of the control signal, followed by addition of a fixed interval to the measured time before the signal is sent to the timer.

FIG. 6 shows a third embodiment of a heart stimulator according to the invention. Here, the heart stimulator consists of a bipolar dual chamber pacemaker 52. A first tip electrode 53 and a first ring electrode 54 are placed in the atrium of a heart 55 and connected to an atrial pulse generator 58 by a first electrode conductor 56 and a second electrode conductor 57. An atrial heart detector 59 is connected in parallel across the pulse generator 58. The atrial pulse generator 59 delivers stimulation pulses, controlled by the control device 60, to the atrium. The atrial heart detector 59 senses the atrium in order to detect any spontaneous atrial responses and sends information on same to the control device 60, whereupon emission of an atrial stimulation pulse can be inhibited. The control device 60 controls the periods in which the atrial heart detector 59 is active.

In the corresponding manner, a second tip electrode 61 and a second ring electrode 62 are placed in the ventricle of the heart 55 and connected to a ventricular pulse generator 65 by a third electrode conductor 63 and a fourth electrode conductor 64 respectively. A ventricular heart detector 66 is connected in parallel across the ventricular pulse generator 65. The ventricular pulse generator 65 delivers stimulation pulses, controlled by the control device 60, to the ventricle. The ventricular heart detector 66 senses the ventricle in order to detect any spontaneous ventricular responses and sends information on same to the control device 60, whereupon emission of a ventricular stimulation pulse can be inhibited. The control device 60 controls the periods in which the ventricular heart detector 59 is active.

The pacemaker 52 contains an impedance meter 67 to adapt delivery of stimulation pulses to the atrium and ventricle so the most natural heart rate possible is achieved.

Conditioning of the impedance signal by the control device 60 is as previously described in conjunction with FIGS. 2 and 4, i.e. with filtration, derivation and generation of a control signal when the derivative signal passes a threshold value dependent on the derivative's minimum value.

In the dual chamber pacemaker 52, a control signal is now used directly by the control device 60

for emitting an atrial stimulation pulse, without any delay, which, after an atrioventricular interval, is followed by a ventricular stimulation pulse. The atrial stimulation pulse provides an extra contribution of blood to the ventricle, resulting in a more natural contraction sequence for the heart. The ventricular stimulation pulse is inhibited if electrical conduction between the atrium and ventricle is working properly and the ventricle contracts spontaneously.

As in the previous embodiment in FIGS. 2 and 4, the dual chamber pacemaker 52 could also contain an activity sensor and a telemetry unit.

In the above embodiment, the derivative of the impedance signal is used for establishing the degree of filling. The impedance signal, with no derivation, can also be used for determining this parameter. Blood flow into the heart can even be used as a parameter as well.

## Claims

1. A rate-responsive pacemaker (1; 52) comprising at least one pulse generator (8; 30; 58) which generates and emits stimulation pulses (29a - e; 50a - d) with a variable stimulation interval ( $I_n$ ) to a heart (4; 55), a measurement device (11; 33; 67) which generates a measurement signal corresponding to blood flow into or the volume of blood in a heart chamber and a control device (9; 35; 60) which controls the pulse generator's (8; 30) stimulation intervals ( $I_n$ ) depending on the measurement signal, characterized in that the control device (9; 35) contains a comparator (22; 39) which, during the heart's blood-filling phase (diastole), compares the measurement signal with a defined threshold value ( $T_n$ ) corresponding to a defined degree of blood filling of the heart chamber and which generates a control signal (28a - e; 49a - e) when the measurement signal exceeds the threshold value ( $T_n$ ), said control signal (28a - e; 49a - e) representing the time elapsing since emission of the last stimulation pulse (29a - e; 50a - d) and controlling the pulse generator's (8; 30; 58) stimulation intervals ( $I_n$ ).
2. A heart stimulator of claim 1, wherein the comparator (22) is connected to the pulse generator, and the pulse generator (8) emits a stimulation pulse (29a - e) when it receives the control signal (28a - e).
3. A heart stimulator of claim 2, wherein the control device (9) further comprises a means (23) for delaying transmission of the control signal (28a - e) to the pulse generator (8) by a

defined delay interval ( I ).

4. A heart stimulator of claim 3, wherein the control device comprises a means for measuring the time elapsing between emission of the latest stimulation pulse (29a - e) and generation of the control signal (28a - e) and the defined delay interval ( I ) is set by the control device (9) according to the time measured.
5. A heart stimulator of claim 1, wherein the control device (35) comprises a timecounter (41), which measures the time elapsing between the latest emitted stimulation pulse (50a - d) and re-generation of the control signal (49a - e), and a timer (42) which is activated when a stimulation pulse (50a - d) is emitted and which times an entered stimulation interval ( $I_n$ ), whereupon an activation signal is transmitted to the pulse generator (30) which emits a stimulation pulse (50a - e), the time measured then being fed to the timer (42) to serve as the next stimulation interval ( $I_{n+1}$ ).
6. A heart stimulator of claim 5, wherein the control device (35) further comprises a means (40) for changing the time serving as the next stimulation interval ( $I_{n+1}$ ) by a defined time interval ( I ).
7. A heart stimulator of claim 6, wherein the control device (35) sets the defined time interval ( I ) depending on the time measured by the timecounter (41).
8. A heart stimulator of claim 5, 6 or 7, wherein the control device (35) comprises an averager, which forms a floating average of a defined number of preceding stimulation intervals ( $I_n$ ), and the current average is sent to the timer (42) to serve as the next stimulation interval ( $I_{n+1}$ ).
9. A heart stimulator of any of the above claims, wherein the measurement device (11; 33; 67) measures impedance in the heart chamber for generating a measurement signal corresponding to the volume of blood in the heart chamber.
10. A heart stimulator of any of the above claims, wherein the control device (9; 35) comprises a differentiator (19; 37) which derives the measurement signal (27; 48), and the comparator (22; 39) compares the derived measurement signal with the threshold value ( $T_n$ ).

11. A heart stimulator of claim 10, wherein the control device (9; 35) comprises a peak value detector (21; 38), which detects the derivative's extreme value ( $M_n$ ) during diastole, and a means (23, 24) for generating the threshold value ( $T_n$ ) so it constitutes a defined part of the extreme value ( $M_n$ ).
12. A heart stimulator of any of the above claims, wherein the heart stimulator (1) comprises an additional measurement device (24; 25; 44), which measures a physiological variable, and a means (23; 24) for determining the threshold value ( $T_n$ ) depending on the physiological variable measured.
13. A heart stimulator of any of the above claims, wherein the control device (9, 35, 60) contains a stimulation interval timer, which times each stimulation interval ( $I_n$ ), and a means for limiting the next stimulation interval ( $I_{n+1}$ ) so it does not become shorter than a first defined part of the timed stimulation interval ( $I_n$ ) nor longer than the timed stimulation interval ( $I_n$ ) by more than a second defined part of the timed stimulation interval ( $I_n$ ).



**FIG 1**

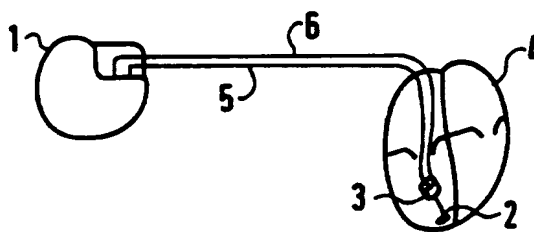


FIG 2

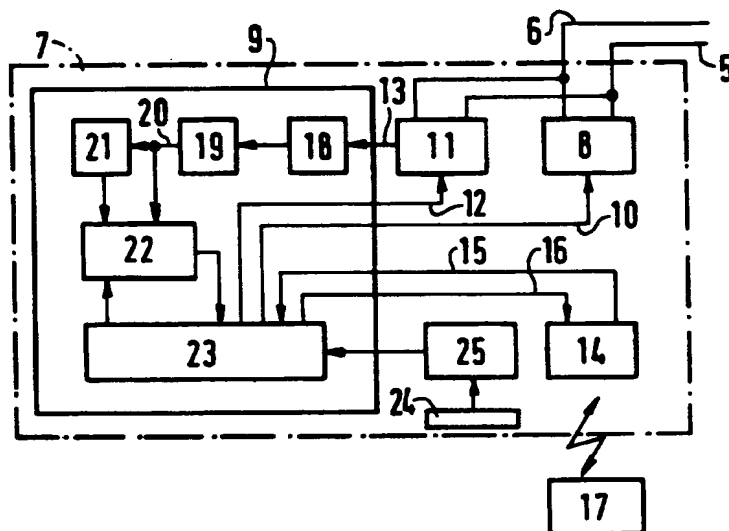


FIG 3

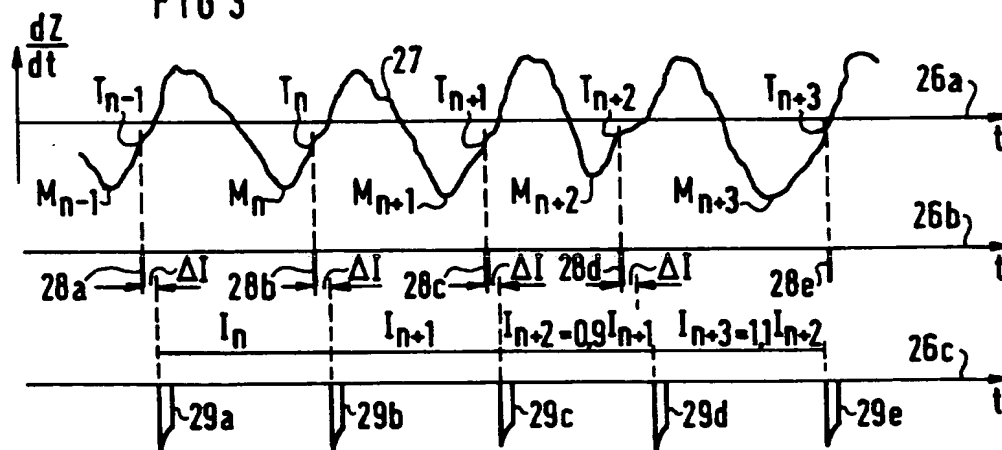


FIG 4

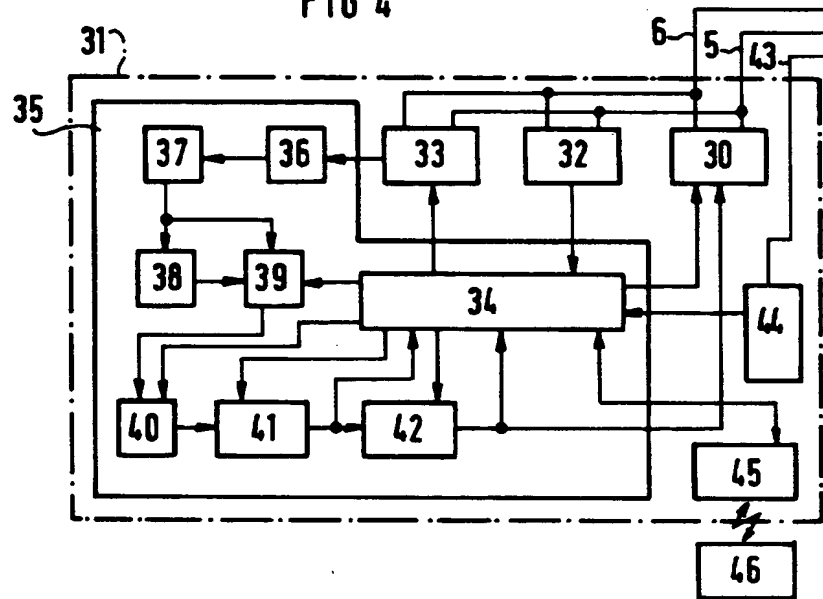


FIG 5

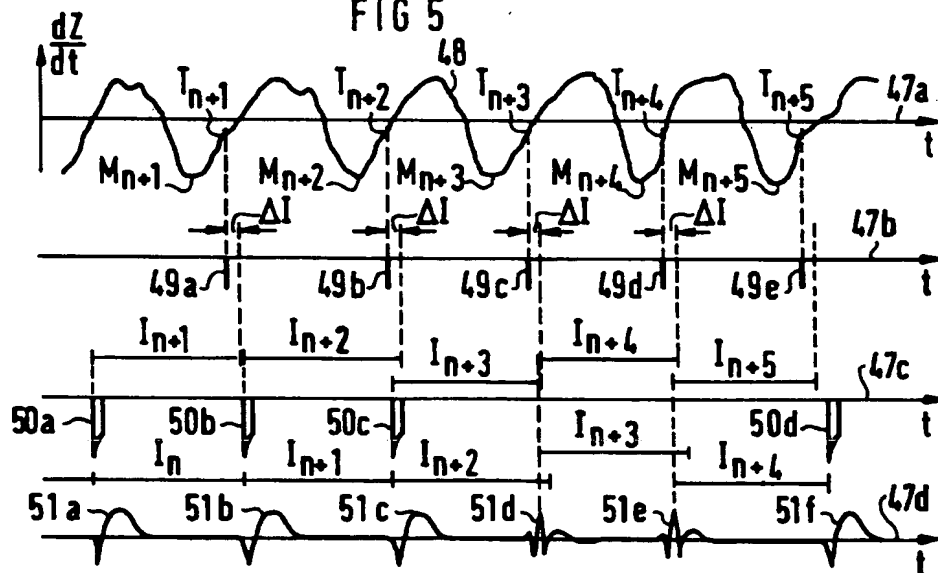
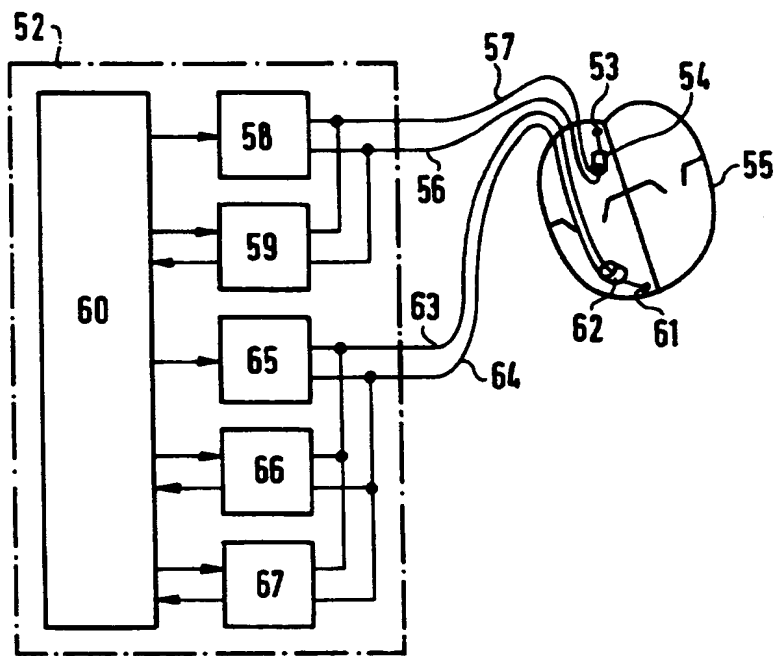


FIG 6





European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number  
EP 93112609.8

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	US-A- 4 733 667 (ARTHUR L. OLIVE ET AL) *figures 1,2* --	1-13	A61N 1/365
A	US-A- 5 137 019 (BRIAN D. PEDERSON ET AL) *figure 3; claim 1* --	1-13	
A	US-A- 5 003 976 (ECKHARD ALT) *column 4, line 37 - line 44* --	1-13	
A	US-A- 4 802 481 (EDWARD A. SCHROEPPEL) *whole document* --	1-13	
A	US-A- 5 139 020 (KEN KOESTNER ET AL) *claim 1* --	1-13	TECHNICAL FIELDS SEARCHED (Int. Cl.5) A61N
A	US-A- 4 686 987 (RODNEY W. SALO ET AL) *whole document* -- -----	1-13	
The present search report has been drawn up for all claims			
Place of search STOCKHOLM		Date of completion of the search 23-12-1993	Examiner WIHLSSON. J
<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			